

Triglycerides

Order information

REF	CONTENT	System-ID	Analyzers on which cobas c pack can be used
20767107 322	Triglycerides (250 tests)	System-ID 07 6710 7	COBAS INTEGRA 400 plus COBAS INTEGRA 800
10759350 190	Calibrator f.a.s. (12 × 3 mL)	System-ID 07 3718 6	
10759350 360	Calibrator f.a.s. (12 × 3 mL, for USA)	System-ID 07 3718 6	
12149435 122	Precinorm U plus (10 × 3 mL)	System-ID 07 7999 7	
12149435 160	Precinorm U plus (10 × 3 mL, for USA)	System-ID 07 7999 7	
12149443 122	Precipath U plus (10 × 3 mL)	System-ID 07 8000 6	
12149443 160	Precipath U plus (10 × 3 mL, for USA)	System-ID 07 8000 6	
10171743 122	Precinorm U (20 × 5 mL)	System-ID 07 7997 0	
10171735 122	Precinorm U (4 × 5 mL)	System-ID 07 7997 0	
10171778 122	Precipath U (20 × 5 mL)	System-ID 07 7998 9	
10171760 122	Precipath U (4 × 5 mL)	System-ID 07 7998 9	
10781827 122	Precinorm L (4 × 3 mL)	System-ID 07 9026 5	
11285874 122	Precipath L (4 × 3 mL)	System-ID 07 9500 3	
05117003 190	PreciControl ClinChem Multi 1 (20 × 5 mL)	System-ID 07 7469 3	
05947626 190	PreciControl ClinChem Multi 1 (4 × 5 mL)	System-ID 07 7469 3	
05947626 160	PreciControl ClinChem Multi 1 (4 × 5 mL, for USA)	System-ID 07 7469 3	
05117216 190	PreciControl ClinChem Multi 2 (20 × 5 mL)	System-ID 07 7470 7	
05947774 190	PreciControl ClinChem Multi 2 (4 × 5 mL)	System-ID 07 7470 7	
05947774 160	PreciControl ClinChem Multi 2 (4 × 5 mL, for USA)	System-ID 07 7470 7	

English

System information

Test TRIGL, test ID 0-010

Intended use

In vitro test for the quantitative determination of the triglycerides concentration in human serum and plasma on COBAS INTEGRA systems.

Summary^{1,2,3,4,5,6}

Triglycerides are esters of the trihydric alcohol glycerol with 3 long-chain fatty acids. They are partly synthesized in the liver and partly ingested in food.

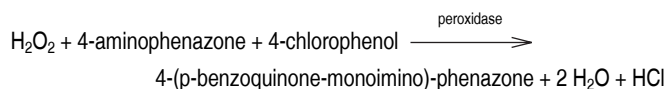
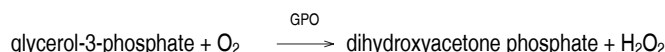
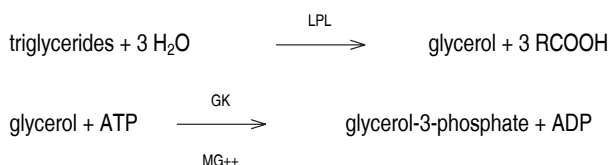
The determination of triglycerides is utilized in the diagnosis and treatment of patients having diabetes mellitus, nephrosis, liver obstruction, lipid metabolism disorders and numerous other endocrine diseases.

The enzymatic triglycerides assay as described by Eggstein and Kreutz still required saponification with potassium hydroxide. Numerous attempts were subsequently made to replace alkaline saponification by enzymatic hydrolysis with lipase. Bucolo and David tested a lipase/protease mixture; Wahlefeld used an esterase from the liver in combination with a particularly effective lipase from *Rhizopus arrhizus* for hydrolysis.

This method is based on the work by Wahlefeld using a lipoprotein lipase from microorganisms for the rapid and complete hydrolysis of triglycerides to glycerol followed by oxidation to dihydroxyacetone phosphate and hydrogen peroxide. The hydrogen peroxide produced then reacts with 4-aminophenazone and 4-chlorophenol under the catalytic action of peroxidase to form a red dyestuff (Trinder endpoint reaction). The color intensity of the red dyestuff formed is directly proportional to the triglyceride concentration and can be measured photometrically.

Test principle⁶

Enzymatic colorimetric test



Reagents - working solutions

R PIPES buffer: 50 mmol/L, pH 6.8; Mg²⁺: 40 mmol/L; sodium cholate: 0.20 mmol/L; ATP: ≥ 1.4 mmol/L; 4-aminophenazone: ≥ 0.13 mmol/L; 4-chlorophenol: 4.7 mmol/L; LPL (microbial): ≥ 83 µkat/L; GK (microbial): ≥ 3 µkat/L; GPO (microbial): ≥ 41 µkat/L; POD (horseradish): ≥ 1.6 µkat/L; preservative; stabilizers

R is in position B.

Precautions and warnings

Pay attention to all precautions and warnings listed in Section 1 / Introduction of this Method Manual.

For USA: For prescription use only.

Reagent handling

Ready for use

Storage and stability

Shelf life at 2-8 °C	See expiration date on cobas c pack label
COBAS INTEGRA 400 plus system	
On-board in use at 10-15 °C	8 weeks
COBAS INTEGRA 800 system	
On-board in use at 8 °C	8 weeks

Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.

Serum

Plasma: Li-heparin and EDTA plasma

EDTA tubes that are less than 1/2 full may cause a negative bias for triglycerides results.

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Centrifuge samples containing precipitates before performing the assay.

Stability in serum:	10 days at 4 °C ⁷
	3 months at -20 °C ⁸
	several years at -70 °C ⁸
Stability in plasma:	15 days at 4 °C ⁹
	3 months at -20 °C ⁸
	several years at -70 °C ⁸

Materials provided

See "Reagents – working solutions" section for reagents.

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator's manual for analyzer-specific assay instructions.

Application for serum and plasma

COBAS INTEGRA 400 plus test definition

Measuring mode	Absorbance
Abs. calculation mode	Endpoint
Reaction mode	R-S
Reaction direction	Increase
Wavelength A/B	512/659 nm
Calc. first/last	17/42
Unit	mmol/L

Pipetting parameters

		Diluent (H ₂ O)
R	120 µL	
Sample	2 µL	28 µL
Total volume	150 µL	

COBAS INTEGRA 800 test definition

Measuring mode	Absorbance
Abs. calculation mode	Endpoint
Reaction mode	R-S
Reaction direction	Increase
Wavelength A/B	512/659 nm
Calc. first/last	17/60
Unit	mmol/L

Pipetting parameters

		Diluent (H ₂ O)
R	120 µL	
Sample	2 µL	28 µL
Total volume	150 µL	

Calibration

Calibrator	Calibrator f.a.s. Use deionized water as zero calibrator.
Calibration mode	Linear regression
Calibration replicate	Duplicate recommended
Calibration interval	Each lot and as required following quality control procedures

Traceability: This method has been standardized against the ID-MS^{a)} method.

a) Isotope Dilution Mass Spectrometry

Quality control

Reference range	Precinorm U, Precinorm U plus, Precinorm L or PreciControl ClinChem Multi 1
Pathological range	Precipath U, Precipath U plus, Precipath L or PreciControl ClinChem Multi 2
Control interval	24 hours recommended
Control sequence	User defined
Control after calibration	Recommended

For quality control, use control materials as listed in the "Order information" section. In addition, other suitable control material can be used.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

Calculation

COBAS INTEGRA analyzers automatically calculate the analyte concentration of each sample. For more details, please refer to Data Analysis in the Online Help (COBAS INTEGRA 400 plus/800 analyzers).

Conversion factor: mmol/L × 88.5 = mg/dL

Note

If the free glycerol is to be taken into account, then 0.11 mmol/L (10 mg/dL) must be subtracted from the patient's triglycerides value obtained.⁸

Limitations - interference

Endogenous unesterified glycerol in the sample will falsely elevate serum triglycerides.

Criterion: Recovery within ± 10 % of initial value.

Icterus:¹⁰ No significant interference up to an I index of 5 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 86 µmol/L or 5 mg/dL).

Hemolysis:¹⁰ No significant interference up to an H index of 600 (approximate hemoglobin concentration: 373 µmol/L or 600 mg/dL).

Drugs: No interference was found at therapeutic concentrations using common drug panels.^{11,12} Exceptions: Ca-Dobesilate, L-α-Methyldopa, Levodopa, and Phenylbutazone cause artificially low triglycerides values at the tested drug level. Dicyclic (Etamsylate) at therapeutic concentrations may lead to false-low results.¹³

No significant interference by physiological ascorbic acid concentrations. Ascorbic acid levels higher than 114 µmol/L (2 mg/dL) decrease the apparent triglycerides concentration significantly.

Acetaminophen intoxications are frequently treated with N-Acetylcysteine. N-Acetylcysteine at a plasma concentration above 333 mg/L and the Acetaminophen metabolite N-acetyl-p-benzoquinone imine (NAPQI) independently may cause falsely low results.

Venipuncture should be performed prior to the administration of Metamizole. Venipuncture immediately after or during the administration of Metamizole may lead to falsely low results. A significant interference may occur at plasma Metamizole concentrations above 0.05 mg/mL.

Triglycerides

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.¹⁴

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

ACTION REQUIRED

Special Wash Programming: The use of special wash steps is mandatory when certain test combinations are run together on COBAS INTEGRA analyzers. Refer to the CLEAN Method Sheet for further instructions and for the latest version of the Extra wash cycle list.

Where required, special wash/carry-over evasion programming must be implemented prior to reporting results with this test.

Limits and ranges

Measuring range

0.1-10 mmol/L (8.85-885 mg/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:10 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 10.

Lower limits of measurement

Lower detection limit of the test:

0.1 mmol/L (8.85 mg/dL)

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying 3 standard deviations above that of a zero sample (zero sample + 3 SD, repeatability, n = 30).

Expected values

According to NCEP¹⁵

Normal range: < 1.70 mmol/L (< 150 mg/dL)

Clinical interpretation according to the recommendations of the European Atherosclerosis Society.¹⁶

	mmol/L	mg/dL	Lipid metabolism disorder
Cholesterol	< 5.18	< 200	No
Triglycerides	< 2.26	< 200	
Cholesterol	5.22-7.77	200-300	Yes if HDL-cholesterol < 0.9 mmol/L (< 35 mg/dL)
Cholesterol	> 7.77	> 300	Yes
Triglycerides	> 2.26	> 200	

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Specific performance data

Representative performance data on the analyzers are given below. Results obtained in individual laboratories may differ.

Precision

Precision was determined using human samples and controls in an internal protocol with repeatability and intermediate precision (2 aliquots per run, 2 runs per day, 20 days). The following results were obtained:

	Level 1	Level 2
Mean	0.97 mmol/L (85.9 mg/dL)	1.63 mmol/L (144 mg/dL)
CV repeatability	1.6 %	1.6 %
CV intermediate precision	1.9 %	1.9 %

Method comparison

Triglycerides values for human serum and plasma samples obtained on a COBAS INTEGRA 700 analyzer using the COBAS INTEGRA Triglycerides (TRIGL) reagent (y) were compared with those determined using commercially available reagents for triglycerides on a COBAS INTEGRA 700 analyzer (COBAS INTEGRA TRIG reagent) (x) and an alternative manufacturer's clinical chemistry system (x). Samples were measured in duplicate. Sample size (n) represents all replicates.

The sample concentrations were between 0.53 and 7.0 mmol/L (46.9 and 620 mg/dL).

COBAS INTEGRA 700 analyzer

Sample size	(n)	222
Correlation coefficient	(r)	0.998
	(r _s)	0.994
Linear regression		y = 1.038x - 0.065 mmol/L
Passing/Bablok ¹⁷		y = 1.013x - 0.030 mmol/L

Alternative system

Sample size	(n)	200
Correlation coefficient	(r)	0.998
	(r _s)	0.996
Linear regression		y = 1.002x + 0.039 mmol/L
Passing/Bablok ¹⁷		y = 1.012x + 0.007 mmol/L

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A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

	Contents of kit
	Volume after reconstitution or mixing
	Global Trade Item Number

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